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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,039	07/18/2003	Subhashis Banerjee	117813-18707	1401

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
01/31/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,039	BANERJEE ET AL.	
	Examiner	Art Unit	
	DAVID J. BLANCHARD	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,12,18,22,23 and 26-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,12,18,22,23 and 26-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/17/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 September 2010 has been entered.

2. Claims 2, 5-11, 13-17, 19-21 and 24-25 have been cancelled.

Claims 57-59 have been added.

3. Claims 1, 3-4, 12, 18, 22-23 and 26-59 are pending and under consideration to the extent that the spoondyloarthropathy is psoriatic arthritis, i.e., applicants' elected species.

Information Disclosure Statement

4. The Information Disclosure Statement (IDS) filed 17 September 2010 has been considered by the Examiner. A signed and initialed copy of the IDS is included with the instant Office Action.

Rejections Withdrawn

5. The provisional rejection of claims 1, 3-4, 12, 18, 22-23, 26-56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 19, 56, 66, 77 and 87 of copending Application No. 11/233,252 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, 2001, IDS reference C64 filed 5/13/08) is withdrawn in view that USSN 11/233,252 has now issued as U.S. Patent

7,588,761 and in view of the new grounds of rejection below over U.S. Patent 7,588,761 (item no. 14 below).

Objections/Rejections Maintained and New Grounds of Rejections

6. The objection to the specification as disclosing various non-provisional US Application numbers whose status has changed and require updating is maintained.

The reply filed 9/17/2010 does not address this objection, however, it is reiterated that USSNs 10/163,657 and 10/622,932 are pending and may require updating during the pendency of the instant application, and the objection is being maintained for convenience.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham **v.** John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. The rejection of claims 1, 3-4, 12, 18, 22-23, 26-56 and now applied to newly added claims 57-59 under 35 U.S.C. 103(a) as being unpatentable over Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001, cited on PTO-892 mailed 9/24/07) in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980, cited on PTO-892 mailed 9/24/07) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, 2001, IDS reference C64 filed 5/13/08) is maintained.

The response filed 9/17/2010 argues that it was known in the art that a dose amount larger than that used for rheumatoid arthritis (RA) was required for treatment of psoriatic arthritis (PsA) for infliximab, citing Corluy et al for support (IDS filed 9/17/10). Corluy et al teach that the dose of infliximab used to treat RA was 3 mg/week and Ogilvie et al teach the dose amount used to treat PsA was 5 mg/kg. Each of claims 18, 34-38, 53 and 57 require a dose amount that is less than or equal to the dose amount described in Keystone as being particularly effective for treating RA, i.e., 40 and 80 mg. Given the knowledge in the art with respect to increased dosing for infliximab for PsA vs RA, one of ordinary skill in the art would not have had an expectation of success in using the dose amounts recited in claims 18, 34-38, 53 and 57 for treating PsA given the teachings of Keystone et al. Applicant reiterates that the examiner has not established how the claimed methods were selected from a finite number of identified, predictable solutions, as required under the guidelines set forth under MPEP 2143 (E) for establishing obviousness under the "obvious to try" rationale. Applicant states that there exists a limitless number of dosage amounts that can be used in any given treatment as there also exists a limitless dosing schedule in terms of how frequently an agent may be delivered. Applicants' arguments have been fully considered but are not found persuasive. Applicants' argument that one of ordinary skill in the art could not predictably extrapolate the dosing regimen for the fully human anti-

TNFα antibody D2E7 in the treatment of RA as taught by Keystone et al to the treatment of PsA, given that the dosing regimen for infliximab is not the same for rheumatoid arthritis and psoriasis is not found persuasive because applicant is relying upon information in which different dosing is used to achieve a desired therapeutic effect for different disorders (e.g., infliximab dosing for RA vs. PsA) as opposed to showing that differences in dosing are unpredictable and that different dosing would have provided no reasonable expectation of success. In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). That is, the evidence merely shows that different dosing regimens may be required to achieve a desired therapeutic effect, not that the different dosing regimens would not be effective and lack a reasonable expectation of success. Further, applicant has not established a nexus between infliximab and the fully human anti-TNFα antibody D2E7 such that one of ordinary skill in the art would accept that infliximab is predictive of the fully human anti-TNFα antibody D2E7. Further, even if one of ordinary skill in the art would find that the different dosing regimens for infliximab in the treatment of RA and PsA is predictive of other neutralizing anti-TNFα therapeutic agents, particularly the fully human anti-TNFα antibody D2E7, the teachings of Keystone et al provide a starting point from which to begin dosing experiments to determine the optimal dosing of fully human anti-TNFα antibody D2E7 for the treatment of psoriasis. The teachings of Keystone et al indicate that subcutaneous administration of the D2E7 antibody was well tolerated and therapeutically effective, particularly at 40 mg every other week. Again, "[A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. KSR, 550 U.S. at ___, 82 USPQ2d at 1397. Applicant continues to overlook the teachings of Keystone et al, which provide clear guidance to the ordinary skilled artisan to subcutaneous administration of the fully human anti-TNFα antibody D2E7 at 20 mg, 40 mg and 80 mg, which was well tolerated and therapeutically effective, particularly at 40 mg every other week. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a

situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 716.02 - § 716.02(g) for a discussion of criticality and unexpected results.

Applicants' arguments that there exists a limitless number of dosage amounts that can be used in any given treatment as there also exists a limitless dosing schedule in terms of how frequently an agent may be delivered have been fully considered but are not found persuasive. Applicants' arguments again overlook the teachings of Keystone et al, which indicate that subcutaneous biweekly administration of the fully human anti-TNFα antibody D2E7 at 20 mg, 40 mg and 80 mg, albeit for the treatment of rheumatoid arthritis, was well tolerated and therapeutically effective, particularly at 40 mg every other week. Thus, while one of ordinary skill in the art would recognize that the optimal dosing regimen for the D2E7 antibody may vary for the treatment of other TNFα-mediated disorders, such as PsA as taught by Ogilvie et al, given the success of D2E7 administered subcutaneously at 20 mg, 40 mg and 80 mg every other week (i.e., biweekly), one of ordinary skill in the art would have been motivated to at least administer the D2E7 antibody or antigen-binding fragments thereof subcutaneously at 20 mg, 40 mg or 80 mg every other week for the treatment of PsA. "[A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. KSR, 550 U.S. at ___, 82 USPQ2d at 1397. Thus, consistent with MPEP 2143(E), the teachings of Ogilvie et al provide an effective therapy for treating PsA using an anti-TNFα antibody, thereby establishing a recognized problem or need in the art and a predictable potential solution to the recognized need or problem and one of ordinary skill in the art could have pursued the known subcutaneous biweekly administration of the known fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et al at 20 mg, 40 mg and 80 mg for the treatment of PsA, since the teachings of Keystone et al indicate that the administered D2E7 antibody was well tolerated and therapeutically effective, particularly at 40 mg every other week. Thus, when considering the teachings of the references relied upon in the rejection, it is unclear how subcutaneous administration at 20 mg, 40 mg and 80 mg every other week (i.e.,

biweekly) of the known fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et al represents a limitless number of dosage amounts and dosing schedule that can be used. Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

Further, since one of ordinary skill in the art would have been led to the fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et al as, it makes little sense that one of ordinary skill in the art would follow the dosing regimen for the chimeric antibody infliximab when using the fully human anti-TNFα antibody D2E7, particularly in view that the subcutaneous biweekly subcutaneous administration of the fully human anti-TNFα antibody D2E7 at 20 mg, 40 mg and 80 mg was known to be well tolerated and therapeutically effective, particularly at 40 mg every other week. Applicants' arguments that the dosing regimen for the chimeric antibody infliximab is predictive and would lead to very different dosages of the fully human anti-TNFα antibody D2E7 compared to the dosing taught by Keystone et al is curious given that applicant also argues that the agent of Ogilvie et al (e.g., Infliximab) and the agent of Keystone et al (e.g., D2E7) have several differences. Again, one of ordinary skill in the art would find it logical and instructive to follow a known dosing regimen for the antibody actually used in the therapy (e.g., the dosing regimen for D2E7 as taught by Keystone), rather than follow the dosing regimen for a different antibody and which might be limited by unwanted immune reaction in human patients. Thus, applicants' argument that the chimeric antibody Infliximab of Ogilvie et al and the fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et al are different, yet one of ordinary skill in the art would ignore the dosing regimen for the fully human anti-TNFα antibody D2E7 of Keystone and administer the D2E7 antibody according to the dosing regimen of Ogilvie et al for a completely different antibody, infliximab, makes little sense and is not found persuasive.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

9. The rejection of claims 1, 3-4, 12, 18, 22-23, 26-56 and now applied to newly added claims 57-59 under 35 U.S.C. 103(a) as being unpatentable over Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001, cited on PTO-892 mailed 9/24/07) in view of Salfeld et al [b] (U.S. Patent 6,509,015 B1, 2/9/1996, IDS reference A2 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980, cited on PTO-892 mailed 9/24/07) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, 2001, IDS reference C64 filed 5/13/08) is maintained.

The applied reference (Salfeld et al [b]) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The response filed 9/17/2010 argues as above and the examiner's remarks above apply here as well and are incorporated herein by reference. It is noted that the instant rejection differs only in the use of Salfeld et al [b], however, Salfeld et al [a] and [b] are equivalent teachings.

Therefore, as discussed supra the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. The rejection of claims 1, 3-4, 12, 18, 22-23, 26-56 and now applied to newly added claims 57-59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 36-39 and 69 of U.S. Patent No. 6,509,015 B1 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001, cited on PTO-892 mailed 9/24/07) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980, cited on PTO-892 mailed 9/24/07) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, 2001, IDS reference C64 filed 5/13/08) is maintained.

The response filed 9/17/2010 argues as above, i.e., the claims invention is not derived from a finite number of possible combinations described in the art and is not an optimization of a known process and there is no motivation to combine the cited references or modify the primary reference given the successful teachings of Ogilvie et al and the knowledge in the art at the time of the invention regarding the dose distinctions for infliximab between RA and PsA. Applicants' arguments have been fully considered but are not found persuasive for the reasons set forth above and incorporated herein by reference, and in view that no terminal disclaimer has been filed.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common

ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,509,015 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

12. The provisional rejection of claims 1, 3-4, 12, 18, 22-23, 26-56 and now applied to newly added claims 57-59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 8-11, 14, 38, 49-50, 52-53 and 55-57 of copending Application No. 11/435,844 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001, cited on PTO-892 mailed 9/24/07) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980, cited on PTO-892 mailed 9/24/07) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, 2001, IDS reference C64 filed 5/13/08) is maintained.

The response filed 9/17/2010 notes that the rejection is provisional in nature and submits that this rejection will be further addressed when the claims are otherwise in condition for allowance. Applicants' remarks are acknowledged, however, the claims are not currently in condition for allowance and no terminal disclaimer has been filed and as such, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/435,844, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

13. The provisional rejection of claims 1, 3-4, 12, 18, 22-23, 26-56 and now applied to newly added claims 57-59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 1, 4-10, 16-21, 78-79, 81, 84, 88, 95, 98 and 100-104 of copending Application No. 10/163,657 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001, cited on PTO-892 mailed 9/24/07) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980, cited on PTO-892 mailed 9/24/07) is maintained.

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A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

14. Claims 1, 3-4, 12, 18, 22-23 and 26-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001, cited on PTO-892 mailed 9/24/07) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980, cited on PTO-892 mailed 9/24/07) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, 2001, IDS reference C64 filed 5/13/08).

Claims 16, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 are drawn to a method for treating a subject suffering from various disorders in which TNFα activity is detrimental comprising administering a pharmaceutical composition comprising an

isolated human anti-human TNFα antibody or antigen-binding fragment thereof that dissociates from human TNFα with a K_d of 1 x 10^{-8} M or less and has a K_{off} of 1 x 10^{-3} s^{-1} or less, as determined by surface plasmon resonance, and neutralizes human TNFα cytotoxicity in a standard in vitro L929 assay with an IC_{50} of 1 x 10^{-7} M or less, or wherein the antibody is D2E7 or an antigen-binding portion thereof and wherein the composition is administered in combination with at least one additional therapeutic agent. Claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 do not teach biweekly, subcutaneous administration of a unit dosage form comprising 10-150 mg, 20-80 mg or about 40 mg of the human anti-human TNFα antibody or antigen-binding fragment thereof for the treatment of psoriasis in a human patient or wherein the additional therapeutic agent is ibuprofen. These deficiencies are made up for in the teachings of Ogilvie et al and Smith et al and Keystone et al.

Ogilvie et al teach a method of treating psoriatic arthritis in patients comprising administering the chimeric anti-TNFα monoclonal antibody, Infliximab, which resulted in a dramatic improvement in arthritis and showed rapid improvement of their psoriatic arthritis (see entire document, particularly Fig. 1).

Smith et al teach that administration of ibuprofen in patients suffering from psoriatic arthritis effectively decreases pain and joint swelling (see entire document).

Keystone et al teach that the fully human anti- TNFα antibody D2E7 administered subcutaneously at 20 mg, 40 mg and 80 mg every other week (i.e., biweekly) was well tolerated and therapeutically effective, particularly at 40 mg every other week (see entire document).

The claims in the instant application are obvious variants of claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 because it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a method for treating psoriatic arthritis in a human subject comprising biweekly, subcutaneous administering the human D2E7 anti-human TNFα antibodies of Salfeld et al [a] at 20 mg, 40 mg or 80 mg (particularly 40 mg) with ibuprofen for the treatment of psoriatic arthritis in a patient.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to produce a method for treating

psoriatic arthritis in a human subject comprising biweekly, subcutaneous administering the human D2E7 anti-human TNFα antibodies of claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 at 20 mg, 40 mg or 80 mg (particularly 40 mg) with ibuprofen for the treatment of psoriatic arthritis in a patient in view of Ogilvie et al and Smith et al and Keystone et al because Ogilvie et al teach a method of treating psoriatic arthritis in patients comprising administering the anti-TNFα monoclonal antibody, Infliximab, which resulted in a dramatic improvement in arthritis and showed rapid improvement of their psoriatic arthritis and Smith et al teach that administration of ibuprofen in psoriatic arthritis patients effectively decreases pain and joint swelling and Keystone et al teach that the fully human anti-TNFα antibody D2E7 administered subcutaneously at 20 mg, 40 mg and 80 mg every other week (i.e., biweekly) was well tolerated and therapeutically effective, particularly at 40 mg every other week. Therefore, one of ordinary skill in the art would have been motivated to administer the D2E7 human anti-human TNFα antibody and antigen-binding fragments thereof of claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 in combination with ibuprofen in order to reduce pain and joint swelling in psoriatic arthritis patients and one of ordinary skill in the art would have been motivated to administer the D2E7 antibody or antigen-binding fragments thereof subcutaneously at 20 mg, 40 mg or 80 mg every other week, which is well tolerated and therapeutically effective according to Keystone et al. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a method for treating psoriatic arthritis in a human subject comprising biweekly, subcutaneous administering the human D2E7 anti-human TNFα antibodies of claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 at 20 mg, 40 mg or 80 mg (particularly 40 mg) with ibuprofen for the treatment of psoriatic arthritis in a patient in view of and Ogilvie et al and Smith et al and Keystone et al.

Claims 1, 3-4, 12, 18, 22-23 and 26-59 are directed to an invention not patentably distinct from claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of commonly assigned U.S. Patent No. 7,588,761. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300).

Commonly assigned U.S. Patent No. 7,588,761, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 57-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed 9/17/2010 has introduced NEW MATTER into the claims. Newly added claims 57-59 recite that the antibody or antigen-binding fragment thereof is administered at a dosage of 10-40 mg. The response points to paragraph 0105 of the as filed disclosure for support of newly added claims 57-59. This has been fully considered but is not found persuasive. The specification at paragraph 0105 discloses a therapeutically or prophylactically effective amount of an antibody or antibody portion of the invention is 10-150 mg, more preferably 20-80 mg and most preferably about 40 mg and the dosage values may vary with the

type and severity of the condition to be alleviated. However, the as filed disclosure as pointed to does not disclose or provide adequate written support for the newly created range of 10-40 mg. The as filed disclosure would not have led the skilled artisan to the presently claimed range of 10-40 mg as opposed to any of the other possible ranges embraced by the broader disclosure as pointed to by applicant. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972). It is noted that entitlement to a filing date does not extend to subject matter, which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed Cir. 1977).

Newly added claims 57-59 recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in newly added claims 57-59, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in newly added claims 57-59 in the specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

17. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached at (571) 272-0839.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be

obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643